EXHIBIT A

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE AMARIN CORPORATION PLC SECURITIES LITIGATION	Case No. 3:19-cv-06601 (BRM) (TJB) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before the Court are three motions: (1) a Motion to Dismiss filed by Amarin Corporation, PLC ("Amarin"), Craig B. Granowitz, Steven Ketchum, John F. Thero, and Joseph S. Zakrzewski (collectively, "Defendants"), seeking to dismiss Gaetano Cecchini, as Trustee of the Gaetano Cecchini Living Trust, and Dan Kotecki's (collectively, "Plaintiffs") Amended Class Action Complaint ("Amended Complaint") (ECF No. 51); (2) Plaintiffs' Motion to Strike exhibits attached to Defendants' Motion to Dismiss (ECF No. 52); and (3) Plaintiffs' Motion to Strike exhibits attached to Defendants' reply (ECF No. 63). Plaintiffs' Amended Complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against Amarin, John F. Thero, Steven Ketchum, and Craig Granowitz (individuals collectively, the "Officer Defendants") and a violation of Section 20(a) of the Exchange Act against John F. Thero, Steven Ketchum, Craig Granowitz, and Joseph S. Zakrzewski (collectively, the "Individual Defendants"). (*See* ECF No. 43 ¶¶ 194–208.) Plaintiffs filed an opposition to Defendants' Motion to Dismiss (ECF No. 53), and Defendants filed a reply to Plaintiffs' opposition. (ECF No. 58.) Further, Defendants filed oppositions to Plaintiffs' Motions to Strike (ECF Nos. 56, 64), and Plaintiffs filed replies to Defendants' oppositions (ECF Nos. 57, 65). Pursuant to Federal Rule of Procedure 78(a), the Court heard Oral Argument on September 9, 2020. (ECF No. 81.) For the reasons set forth below and

for good cause shown, Plaintiffs' Motions to Stay are **DENIED** and Defendants' Motion to Dismiss is **GRANTED without prejudice.**

I. BACKGROUND

A. Factual Background[1]

Amarin is a pharmaceutical company that has, since 2008, focused exclusively on testing and marketing Vascepa, a drug intended to treat heart disease. (ECF No. 43 ¶ 1.) The company is traded on the NASDAQ Global Market under the ticker "AMRN." (*Id.*) Amarin undertook three trials to demonstrate the drug's efficacy. (*Id.* ¶ 2.) The first two trials—the MARINE and ANCHOR trials—were conducted to demonstrate how Vascepa could lower patients' triglyceride levels. (*Id.*) The third and longest trial—the REDUCE-IT trial—was conducted to show Vascepa could reduce patients' major adverse cardiac events. (*Id.*)

The REDUCE-IT trial concluded in the summer of 2018 and while it appeared to show positive results, the trial featured two issues that may have impacted data: (1) the placebo used did not appear to be acting as an inert placebo and (2) the trial data could not explain how the drug was actually reducing negative cardiac events. (*Id.* ¶ 3.) Amarin decided to publish the REDUCE-IT trial's apparently positive results while keeping both issues with the trial a secret. (*Id.* ¶ 5.) At a conference call following the trial, Defendants stated the trial's results exceeded expectations and were "the single most, significant advance in preventive cardiovascular drug therapy since the advent of statin therapy" while also priding it was "an overall robust study result." (*Id.* ¶ 5.) As a result of this announcement, Amarin's share price rose 433% over the course of two days. (*Id.*)

[1] For the purposes of this Motion to Dismiss, the Court accepts the factual allegations in the Amended Complaint as true and draws all inferences in the light most favorable to Plaintiffs. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008).

Following this price spike, "Amarin's top officers seized on the opportunity to sell an unprecedented number of shares." (*Id.* ¶ 6.) But when the issues with the REDUCE-IT trial were disclosed at an American Heart Association ("AHA") conference on November 10, 2018, where top health experts noted the placebo "may have helped overstate Vascepa's true effect," share prices dropped 27% over the course of a few days. (*Id.* ¶ 7.) Plaintiffs and other Class members seek to recover the damages they suffered as a result of "Defendants' fraudulent acts and omissions." (*Id.* ¶ 8.)

The Court has jurisdiction over this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331. (*Id.* ¶ 9.) Lead Plaintiff Gaetano Cecchini, as Trustee of the Gaetano Cecchini Living Trust, purchased Amarin American Depository Shares ("ADS") during the Class Period, and was damaged as a result. (*Id.* ¶ 13.) Defendant Amarin is a biotechnology company with its headquarters in Dublin, Ireland and its U.S. office at 1430 Route 206, Bedminster, New Jersey 07921. (*Id.* ¶ 14.)

Plaintiffs allege the Individual Defendants, "as senior executive officers and directors of Amarin, were privy to confidential and proprietary information concerning Amarin, its operations, product, finances, financial condition, and present and future business prospects." (*Id.* ¶ 20.) According to Plaintiffs, "[b]ecause of their possession of such information, the Officer Defendants knew or recklessly disregarded that the adverse facts contradicting their misrepresentation and relating to their omissions had not been disclosed to, and were being concealed from, the investing public."[2] (*Id.*)

[2] Plaintiffs spend several pages describing heart disease in general, Vascepa's function, the MARNIE trial, the ANCHOR trial, and the REDUCE-IT trial (ECF No. 43 ¶¶ 25–46.) Plaintiffs detail other information in its Amended Complaint as well, including: FDA rejection of expanded approval of Vascepa based on the ANCHOR trial (*id.* ¶¶ 47–63); a previous securities class action based on Amarin shares (*id.* ¶¶ 64–68); and the conclusion of the REDUCE-IT trial (*id.* ¶¶ 69–71.)

On September 24, 2018, "the Class Period began when Amarin announced the results of the REDUCE-IT trial." (*Id.* ¶ 71.) Defendants reported the REDUCE-IT trial showed using Vascepa, when compared to a placebo, resulted in a 25% reduced risk of major adverse cardiovascular events. (*Id.*) They noted the trial showed "that pure EPA Vascepa at 4 grams/day can provide additional cardiovascular risk reduction benefit on top of LDL-C control with standard care statin therapy in studied patients." (*Id.*) During a conference call that same day, Amarin officers further touted the "truly remarkable" results of the REDUCE-IT study, emphasizing the risk reduction the drug offered, which was "supported by robust demonstrations of efficacy across multiple secondary endpoints." (*Id.* ¶ 72.) Defendants stated the results "represent[ed] a greater reduction than demonstration on top of statin therapy for any other drug" and "positions Vascepa to be first to market in addressing a large unmet medical need." (*Id.*) During the conference, Defendants "indicated that they had reviewed the entire data set, but explained that they were withholding the remaining results for the forthcoming AHA Conference presentation." (*Id.* ¶ 73.)

Plaintiffs allege the statements made by Defendants were misleading when made in the context of the FDA's prior concerns with the mineral oil placebo in the ANCHOR trial, the FDA's rejection of the ANCHOR supplemental new drug application ("sNDA"), the FDA's direction to Amarin to monitor the placebo arm in the REDUCE-IT trial, the allegations in the *Sklar* Action regarding the use of mineral oil as a placebo, Regulation 21 C.F.R. 201.302(G)(a) (2018), and recent failed cardiovascular studies of omega-3 products. (*Id.* ¶ 83.) Plaintiffs allege these statements were misleading because Defendants omitted several facts from these communications. (*Id.*)

These omissions include not disclosing that the mineral oil used as a placebo "may have interfered with patients' cholesterol-lowering statins" which impacted the relative risk reduction

of Vascepa. (*Id.*) Plaintiffs allege omissions were made about the mineral oil that affected various aspects of the patient's studied metrics—that is, the mineral oil raised various metrics across groups in the REDUCE-IT trial, making Vascepa seem more effective in comparison to the placebo arm of the study. (*Id.*) According to Plaintiffs, even though Defendants were aware of the issues with the REDUCE-IT trial, they "decided to conceal [that] information from the market to drive up Amarin's share price and keep it inflated." (*Id.* ¶ 84.)

Plaintiffs allege "publicizing only the efficacy results that claimed a 25% reduction of major adverse cardiovascular events on top of statin therapy was false and misleading." (*Id.* ¶ 139.) Relatedly, Plaintiffs assert as of September 24, 2018, when Defendants announced the REDUCE-IT trials' results, they "had already analyzed the full REDUCE-IT trial data and thus knew that publicizing the results without important caveats would likely mislead investors." (*Id.* ¶ 140.) Further, "Amarin and the Officer Defendants' public statements confirm that the Company had the full data when Amarin announced the results on September 24, 2018." (*Id.* ¶ 143.) Plaintiffs point to statements where Amarin's CEO and CSO, who both had access to the full data set before it was released to the public, said they were not going to disclose additional details or "talk too much about the results of the REDUCE-IT study because" they were saving those further details for presentation at the AHA Conference. (*Id.* ¶¶ 144–48.) According to Plaintiffs, Defendants, knowing the full results of the REDUCE-IT trial, mislead investors by choosing not to "provide the necessary qualifications" before the full results were released at the AHA Conference. (*Id.* ¶ 151.) Even if Defendants had not reviewed the full dataset "about which they spoke during the Class Period, they were deliberately reckless in making statements about such data when they could have easily reviewed it in the database to which they had access." (*Id.* ¶ 152.)

Plaintiffs allege the fact that Defendants first chose to disclose the issues with the REDUCE-IT trial at the AHA Conference "confirms that Defendants were aware they were important." (*Id.* ¶ 154.) Plaintiffs refer to articles from the New England Journal of Medicine and Forbes which summarize the concerns of various cardiologists once the full results of the REDUCE-IT trial became available. (*Id.* ¶¶ 157–60.) Plaintiffs also assert that Defendants' use of mineral oil—an allegedly biologically active oil—as a placebo, was nothing new since the FDA, as early as 2013, had previously scrutinized Defendants for using the oil as a placebo. (*Id.* ¶¶ 161–65.) Lastly, Plaintiffs note Defendants filed a 10-Q where they represented the report did not contain any untrue statements of material fact, even though, according to Plaintiffs, "Thero's possession of the full analyzed REDUCE-IT trial data set, and appreciation of the aberrations in the placebo arm of the data . . . suggests that Thero was either reckless in making his Sarbanes-Oxley certification" or had actual knowledge the filing contained untrue statements of material fact. (*Id.* ¶¶ 166–67.)

B. Procedural Background

On February 22, 2019, Plaintiffs filed a Complaint against Amarin, John F. Thero, and Steven Ketchum. (ECF No. 1.) On July 22, 2019, Plaintiffs filed an Amended Class Action Complaint ("Amended Complaint"). (ECF No. 43.) The Amended Complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against Defendants (Count One) and a violation of Section 20(a) of the Exchange Act against the Individual Defendants (Count Two). (*See id.* ¶¶ 194–208.)

On October 4, 2019, Defendants filed a Motion to Dismiss Plaintiffs' Amended Complaint. (ECF No. 51.) On November 26, 2019, Plaintiffs filed a Motion to Strike certain exhibits contained within Defendants' Motion to Dismiss. (ECF No. 52.) On November 26, 2019, Plaintiffs filed an

opposition to Defendants' Motion to Dismiss. (ECF No. 53.) On December 23, 2019, Defendants filed an opposition to Plaintiffs' Motion to Strike. (ECF No. 56.) On January 3, 2020, Plaintiffs replied. (ECF No. 57.) On January 10, 2020, Defendants filed a reply to Plaintiffs' opposition. (ECF No. 58.) On January 23, 2020, Plaintiffs filed a Motion to Strike exhibits and related arguments in Defendants' reply. (ECF No. 63.) On February 4, 2020, Defendants filed an opposition to Plaintiffs' Motion to Strike. (ECF No. 64.) On February 11, 2020, Plaintiffs filed a reply. (ECF No. 65.)

II. LEGAL STANDARD

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the

pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a probability requirement." *Id.* (quoting *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). However, courts are "not compelled to accept 'unsupported conclusions and unwarranted inferences,'" *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (quoting *Schuylkill Energy Res. Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), nor "a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286.

While, as a general rule, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "document *integral to or explicitly relied upon* in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997 (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir.

1996)).

III. DECISION

Before deciding the Motion to Dismiss, the Court must determine which exhibits are proper to consider at this stage.

A. Plaintiffs' Motions to Strike

i. Plaintiffs' First Motion to Strike

Plaintiffs filed two motions to strike exhibits Defendants attached to their Motion to Dismiss and Reply pursuant to Fed. R. Civ. P. 12(f)(2). The first Motion to Strike asks the Court to strike twenty-two exhibits, Exhibits B through W, that Defendants submitted with their Motion to Dismiss and the portions of Defendants' briefs that discuss them. (ECF No. 52-1 at 2–3.) The challenged exhibits are:

- Exhibit B: Excerpts from Amarin Form 10-Q for the period ending September 30, 2013 (filed Nov. 7, 2013);
- Exhibit C: Excerpts from Amarin's Form 10-K for the period ending December 31, 2018 (filed Feb. 27, 2019);
- Exhibit D: Excerpts from *FDA Briefing Document Endocrinologic and Metabolic Drugs Advisory Committee Meeting* (Oct. 16, 2013);
- Exhibit E: Excerpts of the transcript from the FDA's Endocrinologic and Metabolic Drugs Advisory Committee Hearing of Wednesday, October 16, 2013 (the "AdCom");
- Exhibit F: Stipulation and Order of Settlement, *Amarin Pharma, Inc, et al. v. United States Food & Drug Administration, et al.*, 15-cv-3588 (PAE), ECF No. 84 (S.D.N.Y. Mar. 8, 2016);

- Exhibit G: Transcript of Amarin Conference Call at American Heart Association Scientific Conference, November 10, 2018 (from Bloomberg);
- Exhibit H: Amarin press release titled "REDUCE-IT Cardiovascular Outcomes Study of Vascepa (icosapent ethyl) Capsules Met Primary Endpoint," dated September 24, 2018;
- Exhibit I: Transcript of Vascepa REDUCE-IT Study Result Call (Sept. 24, 2018) (from Bloomberg);
- Exhibit J: Excerpts from Amarin Form 10-Q for the period ending September 30, 2018 (filed Nov. 1, 2018);
- Exhibit K: Deepak L. Bhatt, M.D., M.P.H., et al., *Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia*, 380 N. Engl. J. Med. 11 (2018);
- Exhibit L: Amarin Corp., *How does Vascepa Work? Potential Mechanism of Action for Vascepa*, July 15, 2019;
- Exhibit M: Matthew Herper, *Amarin's Fish-Oil-Derived Drug Shows Great Promise—With Big Caveats*, Forbes Healthcare (Nov. 10, 2018) (the "Forbes Article");
- Exhibit N: Deepak L. Bhatt, M.D., M.P.H., et al., *Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglceridemia*, 380 N. Engl. J. Med. 11 (Jan 3, 2019);
- Exhibit O: Amarin press releases titled "Amarin Provides Preliminary 2018 Results and 2019 Outlook," dated January 4, 2019 (referenced AC at 1); "New Updates for the American Diabetes Association's 2019 Standards of Medical Care in Diabetes Incorporate Findings from the REDUCE-IT Cardiovascular Outcomes Study,"

dated March 28, 2019; and "New 2019 Updates to the European Society of Cardiology's and European Atherosclerosis Society's Guidelines for the Management of Dyslipidaemias Incorporate Findings from the REDUCE-IT Cardiovascular Outcomes Study," dated September 3, 2019;

- Exhibit P: Deepak L. Bhatt, M.D., M.P.H., et al., *Effects of Icosapent Ethyl on Total Ischemic Events*, 73 J. Am. C. Cardiology 2791 (2019);
- Exhibit Q: John M. Mandrola, M.D., *Pure Fish Oil Lowers CVS Risk Even If We Don't Understand How*, Medscape (Nov. 11, 2018);
- Exhibit R: Taylor Carmichael, *How Fishy Is This Fish Oil Pill?*, The Motley Fool (Oct. 2, 2019) (the "Motley Fool Article");
- Exhibit S: DoctoRx, *Amarin's REDUCE-IT Trial: Something Fishy?*, Seeking Alpha ("Seeking Alpha Article");
- Exhibit T: Excerpts from Amarin's Form 10-K for the period ending December 31, 2015 (filed Feb. 25, 2016);
- Exhibit U: Form 4s filed by John F. Thero, Joseph T. Kennedy, Michael W. Kalb, Joseph S. Zakrzewski, David Stack, Kristine Peterson, Jan van Heek, Lars G. Ekman, and Patrick J. O'Sullivan;
- Exhibit V: Historical Stock chart of AMRN for period of September 15, 2018 to November 15, 2018; and
- Exhibit W: Excerpts from Amarin's Schedule 14A Proxy Statement, dated April 25, 2019

(ECF No. 51-1 at 2–4.) Defendants also attached two additional exhibits to their reply in further support of their motion to dismiss:

- Exhibit X: FDA News Release: FDA approves use of drug to reduce risk of cardiovascular events in certain adult patient groups, dated December 13, 2019; and
- Exhibit Y: Transcript of Amarin Q3 2018 Earnings Call (Nov. 1, 2018) (from Bloomberg)

(ECF No. 59 at 2.) In their reply, Defendants clarify "Amarin has no objection if this Court chooses to disregard Exhibits C-I, K-L, and N-S." (ECF No. 58 at 15.) Therefore, the Court's analysis of both motions will be limited to the Amended Complaint, Amarin's public filings (Exs. B, J, T, and Y), the Forbes blog (Ex. M), documents showing stock sales (Exs. U, V, and W), and the FDA's press release granting expanded approval (Ex. X).

Plaintiffs contend the Court should not consider "evidence outside the amended complaint unless (1) the document is incorporated by reference, or (2) the adjudicative fact at issue is subject to judicial notice." (*Id.* at 2 (citing *Institutional Inv'rs Grp. V. Avaya, Inc.*, 564 F.3d 242, 260 n.31 (3d Cir. 2009).) Plaintiffs argue "Defendants make no effort whatsoever to explain which Exhibits they allege are incorporated by reference and which of these Exhibits are properly subject to judicial notice to establish a specific adjudicative fact." (*Id.*) Alternatively, Plaintiffs asks the Court to "convert the Defendants' motion into a motion for summary judgment pursuant to Rule 12(d) and provide Plaintiffs with an opportunity to respond after conducting discovery." (*Id.* at 3.)

Defendants argue Plaintiffs' first Motion to Strike is procedurally improper. (ECF No. 56 at 3–4.) In response, Plaintiffs argue its Motion to Strike is procedurally proper "under Rule 12(d), FRE 201, and the Court's inherent authority" but does not argue its Motion to Strike is proper under Rule 12(f). (ECF No. 57 at 15.)

Federal Rule of Civil Procedure 12(f) provides: "[t]he court may strike from a *pleading* an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ.

P. 12(f) (emphasis added). Plaintiffs move to strike exhibits attached to Defendants' Motion to Dismiss. (*See* ECF No. 52.) The Federal Rules of Civil Procedure include a list of permitted "pleadings," which does not include motions, briefs supporting motions, or attached exhibits, and addresses motions under a separate subsection. *See* Fed. R. Civ. P. 7. Plaintiffs' motion to strike does not attack a pleading, rather it attacks exhibits attached to Defendants' motion to dismiss, which is procedurally improper. *See, e.g.*, *Gresko v. Pemberton Township Board of Education*, Civ. A. No. 19-00638, 2020 WL 6042317, at *3 (D.N.J. Oct. 13, 2020); *Litgo New Jersey, Inc. v. Martin*, Civ. A. No. 06-2891, 2012 WL 32200, at *11 (D.N.J. Jan. 5, 2012), *aff'd sub nom. Litgo New Jersey Inc. v. Comm'r New Jersey Dep't of Env't Prot.*, 725 F.3d 369 (3d Cir. 2013) ("[M]otions to strike are generally directed at pleadings, *see* Fed. R. Civ. P. 12(f), not at motions, briefs, or other filings . . . ."); *Faulman v. Sec. Mut. Fin. Life Ins. Co.*, 2006 WL 2482926, at *3 (D.N.J. Aug. 28, 2006). Therefore, Plaintiffs' first Motion to Strike is denied under Fed. R. Civ. P. 12(f).

Next, the Court will address Plaintiffs' argument that "the Court should convert Defendants' motion into a motion for summary judgment pursuant to Rule 12(d)." (ECF No. 52-1 at 3.) Plaintiffs argue Defendants' incorporation by reference demand "should be rejected for a failure to explain how Plaintiffs' claims are 'based on' each of the 22 Exhibits." (ECF No. 52-1 at 8 (citing *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014)).) Plaintiffs argue "nine of Defendants' Exhibits—F, L, N, O, P, Q, R, T, and U—were never cited in the [Amended Complaint]." (*Id.* at 9.)

Defendants argue their motion "identifies every factual assertion for which a document is cited, the specific document, and in most instances the specific page number of the specific document, in which the respective fact is contained." (ECF No. 56.) Defendants also argue

Exhibits B, C, J, T, U, and W, SEC filings, are documents that the Court can consider in deciding the motion. (ECF No. 56 at 17–22.) The Court will only consider arguments for Exhibits B, J, T, U, and W.

In their reply, Plaintiffs argue several of Defendants' exhibits should be stricken because they were improperly submitted. (ECF No. 57 at 5–14.) These include Exhibit C (Amarin's 2018 Form 10-k); Exhibits D and E (the FDA Documents); Exhibit F (the Amarin/FDA Dispute); Exhibits G and I (Conference Call Transcripts); Exhibits B, H, J, and T (Amarin SEC filings and Press Release); Exhibits K and N (the NEJM Article); Exhibits L, M, N, O, P, Q, R and S (Amarin Publications and Articles Stating Reactions to REDUCE-IT Results); Exhibits U and W (Forms 4 and Schedule 14A); and Exhibit V (the Stock Price Chart). (*See id.*) The Court will only consider Plaintiffs' arguments regarding Exhibits B, J, T, M, U, V, and W for the first Motion to Strike.

When considering a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), district courts "generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt*, 770 F.3d at 249 (citing *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). An exception to this general rule is "that a document *integral to or explicitly relied* upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *Id.* (internal quotation marks omitted) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426). "[W]hat is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426 (3d Cir. 1997) (citing *Shaw*, 82 F.3d at 1220).

It is also "axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Olson v. Ako*, 724 F. App'x 160, 166 (3d Cir. 2018) (citation omitted); *Bolden*

v. Nat'l Fin. Servs. LLC, Civ. A. No. 04-5527, 2005 WL 8175134, at *6 (D.N.J. May 23, 2005) (noting that a plaintiff "cannot rely on new facts not alleged in their Complaint to defeat a motion to dismiss"). However, Federal Rule of Evidence 201(b) allows a court "to take judicial notice of facts that are not subject to reasonable dispute in that they are either: (1) generally known within the territorial jurisdiction of the trial court; or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 390 (D.N.J. 2010) (quoting *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002)) (alterations omitted). "Conversely, judicial notice is improper if a legitimate question exists as to the underlying source of the information." *Id.*

Taking notice of matters of public record does not convert a motion to dismiss into a motion for summary judgment so long as the facts are noticed in accordance with the Federal Rules of Evidence. *Intri-Plex Techs., Inc. v. Crest Grp., Inc.*, 499 F.3d 1048, 1052 (9th Cir. 2007). However, it "is improper for a court to take judicial notice of the veracity and validity of a public document's contents when the parties dispute the meaning and truth of the contents." *See, e.g.*, *Lee v. City of L.A.*, 250 F.3d 668, 690 (9th Cir. 2001) (reversing a district court's grant of a motion to dismiss where the court not only took judicial notice of undisputed matters of public record but also took judicial notice of "disputed facts stated in public records" and relied on the validity of those facts in deciding the motion to dismiss).

1. Amarin's Public Filings (Exs. B, J, and T)

Plaintiffs assert the reasons for introducing Exhibits B, J, and T—to show Defendants had disclosed the fact that (1) the placebo might not be inert and (2) the mechanism of action for EPA had not been identified—is irrelevant "because the [Amended Complaint] alleges that Defendants failed to disclose the specific Adverse REDUCE-IT Data, generated in 2018, which data itself

called into question the relative risk reduction seen in the REDUCE-IT trial." (ECF No. 57 at 9.) Plaintiffs also argue "Exs. B and T were not [incorporated by reference] because Ex. T was never cited in the [Amended Complaint], Ex. B simply provided background facts, and neither formed the basis of the claims." (*Id.*)

Defendants argue the Court may take judicial notice of Exhibit B, which provides excerpts from Amarin's Form 10-Q for the quarter ending September 30, 2018 (filed with the SEC on November 7, 2013), because "the portion of Exhibit B that is quoted in the MTD Brief is also quoted in the Complaint." (ECF No. 56 at 17 (citing Am. Compl. ¶ 62).) Further, Defendants argue Exhibit B, as an SEC filing, is the kind of document that courts routinely judicially notice. (*Id.* at 18.) Defendants similarly assert "the Complaint plainly relies on Exhibit J, Exhibit J is integral to the Complaint, and Exhibit J is subject to judicial notice." (*Id.* at 19.) Defendants also make similar arguments for the judicial notice of Exhibit T. (*Id.* at 20.)

The Third Circuit permits a district court to judicially notice SEC filings and public disclosures. *In re NAHC, Inc. Sec. Litig.*, 306 F.3d at 1331 (affirming district court's decision to judicially notice documents "comprising Company SEC filings and press releases" relied upon in the Complaint, "documents filed with the SEC, but not relied upon in the Complaint," and "stock price data compiled by the Dow Jones news service"); *Ieradi v. Mylan Lab'ys, Inc.*, 230 F.3d 594, 600 n.3 (3d Cir. 2000) (taking judicial notice of "the opening and closing stock prices on the New York Stock Exchange for Mylan . . . reported by Quotron Chart Service"); *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 273 (D.N.J. 2007) (taking judicial notice of an SEC Investigation Notice "duly filed with by Intelligroup with the SEC" among several other documents); *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 530 n.1 (W.D. Pa. 2019) (noting SEC filings "are documents of which the Court may take judicial notice"). However, when judicially noticing documents filed

with the SEC, the documents cannot be offered "to prove the truth of their contents but only to determine what the documents stated." *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (quoting *Kramer v. Timer Warner, Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)).

Exhibits B and J, which are composed of excerpts from Amarin's Form 10-Q, are subject to judicial notice. Form 10-Qs are an SEC filing routinely subject to judicial notice in this Circuit. *In re NAHC, Inc. Sec. Litig.*, 306 F.3d at 1331; *In re PTC Therapeutics, Inc. Sec. Litig.*, Civ. A. No. 161124, 2017 WL 3705801, at *3 n.5 (D.N.J. Aug. 28, 2017) (noting PTC's 10-Q's "are clearly subject to judicial notice"). Further, Defendants offer Exhibits B and J only to show "what the document[] stated"—that they disclosed the potential risk that mineral oil may impact the REDUCE-IT trials results—not to "prove the truth" of the Form 10-Q's contents. *See Oran*, 226 F.3d at 289. For similar reasons, the Court will also consider Exhibit T, which includes excerpts from Amarin's Form 10-K. Like Exhibits B and J, Exhibit T is a kind of SEC filing commonly subject to judicial notice. *In re Johnson & Johnson Derivative Litig.*, 865 F. Supp. 2d 545, 550 (D.N.J. 2011) (district court taking judicial notice of Form 10-k filing under Federal Rule of Evidence 201 because "the court may take judicial notice of facts gathered from 'sources whose accuracy cannot reasonably be questioned,'" which has been interpreted by the Third Circuit "to permit judicial notice of properly authenticated documents filed with the SEC") (internal citations omitted). Plaintiffs' argument that Exhibits B and T are not cited in the Amended Complaint does not impact the Court's finding here, since a court may judicially notice facts not relied upon in the complaint. *See NAHC, Inc. Sec. Litig.*, 306 F.3d at 1331. Accordingly, the Court will judicially notice the facts contained within Exhibits B, J, and T.

2. The Forbes Blog (Ex. M)

Plaintiffs argue Exhibit M, among other documents the Court is not considering, was introduced by Defendants "to present allegedly positive opinions . . . which were contrary to the negative viewpoints in the [Amended Complaint]." (ECF No. 57 at 11.) Plaintiffs also argue Exhibit M is being offered for a hearsay purpose. (*Id.*) Lastly, Plaintiffs argue Exhibit M was "cited in the [Amended Complaint] to explain the significance of and the market's reaction to the Adverse REDUCE-IT Data . . . however, [this] document did not contain Defendants' misleading statements, and thus Plaintiffs' claims are not based on them." (*Id.* at 11–12.) Even if Exhibit M was incorporated, Plaintiffs contend, "it would be improper for the Court to consider them for the truth of the matters asserted." (*Id.* at 12.)

Defendants argue Exhibit M was cited extensively by Plaintiffs in the Amended Complaint and forms "the entire basis for Plaintiffs' claim." (ECF No. 56 at 28.) Defendants assert they "may therefore cite to the Forbes article in their Motion to Dismiss to contradict Plaintiffs' characterization of the article" and demonstrate the article concludes Vascepa reduces risk of death, shows doctors interviewed in the article were impressed with the REDUCE-IT trial's results, and discloses "that one doctor who was critical of the REDUCE-IT results was conducting a study of a competing drug." (*Id.*)

Plaintiffs refer to Exhibit M throughout their Amended Complaint. (*See* ECF No. 43 ¶¶ 94–102, 158–60.) The Amended Complaint quotes entire paragraphs of the article to highlight how cardiologists surveyed felt the results of the REDUCE-IT trial could have been exaggerated by using mineral oil as a placebo. (*Id.* ¶¶ 95–96.) The Amended Complaint also quotes the cardiologists surveyed in the article at length. (*Id.* ¶¶ 97–101.) While the Amended Complaint cites

to Exhibit M extensively to describe the market's reaction to the REDUCE-IT trial's full results (*id.* ¶¶ 94–102, 104), it also relies on the article to allege Defendants knew publicizing limited results of the REDUCE-IT study would provide misleading information to its investors as part of its allegations for scienter. (*Id.* ¶¶ 158–60.) Therefore, Exhibit M was explicitly relied upon in the Amended Complaint and served as the basis of Plaintiffs' claims. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426. Further, the Court would not be considering the document for the truth of the matters in the Forbes article, but rather to "determine *what* the documents stated"—that is, to show the article stated, among other things, that Vascepa reduced the risk of dying despite the caveats presented by the mineral oil placebo. *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (citing *Kramer*, F.2d at 774). Accordingly, the Court finds Exhibit M was incorporated by reference in the Amended Complaint and will be considered in deciding the Motion to Dismiss.

3. Documents Showing Stock Sales (Exs. U, V, and W)

Plaintiffs argue "the Court may not take judicial notice of the truth of the statements in [Exhibits U and W] *i.e.*, that the Forms 4 accurately reflect all trades made by Defendants or that the proxy statement accurately reflects the executives' total compensation" because "the only fact Easily Verifiable from these forms is what Defendants reported to the SEC." (ECF No. 57 at 12.) In addition, Plaintiffs argue Exhibit U was neither cited nor referenced in the Amended Complaint, and Exhibit W, while cited in the Amended Complaint, was not integral to the complaint. (*Id.* at 13.) Lastly, Plaintiffs argue the Court may not take judicial notice of Exhibit V "because there is nothing that indicates its source, so it is not Easily Verifiable." (*Id.*)

Defendants argue Exhibit U should not be stricken because "Courts in the Third Circuit routinely consider Form 4s in order to both test the accuracy of a plaintiff's stock sales allegations

and to determine whether the alleged sales were made pursuant to a 10b5-1 plan." (ECF No. 56 at 20–21.) Defendants assert the Court can consider Exhibit W because "the Complaint cites and explicitly relies on Exhibit W in its allegations concerning Amarin's bonus compensation program and the claim that Defendants would supposedly receive higher bonuses based upon the results of REDUCE-IT." (*Id.* at 21.) Defendants also argue the Motion to Dismiss cites Exhibit W only to show "the bonuses in question were immaterial to Defendants in light of their overall compensation and therefore could not have provided a motive for fraud." (*Id.* at 22.) Lastly, Defendants contend Exhibit V, which is a historical stock chart from Yahoo Finance cited to show Defendants "did not sell near the Class Period highs of Amarin's stock price," because the information "is a matter of public record and courts routinely take judicial notice of such information." (*Id.* at 24.)

Exhibit U contains SEC Form 4s showing Defendants' stock sales. In the Amended Complaint, Plaintiffs detail several instances of suspicious insider trading (ECF No. 43 ¶¶ 108–121) to allege Defendants had "the opportunity and financial motive to artificially inflate the price of Amarin shares, supporting the compelling inference of scienter" (*id.* ¶ 107). While Plaintiffs do not explicitly cite or rely upon the SEC Form 4s in the Amended Complaint, courts in the Third Circuit consider Form 4s to assess insider trading allegations on motions to dismiss. *In re Hertz Glob. Holdings, Inc. Sec. Litig.*, Civ. A. No. 13-7050, 2017 WL 1536223, at *22 n.10 (D.N.J. Apr. 27, 2017), *aff'd sub nom. In re Hertz Glob. Holdings Inc*, 905 F.3d 106 (3d Cir. 2018) (considering Form 4s in deciding motion to dismiss and noting "it can take judicial notice of the public filings showing that the challenged sales by the defendants were made pursuant to 10b5-1 plans") (citations omitted); *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 623 (D.N.J. 2002); *In re Merck Co., Inc., Sec., Derivative & "Erisa" Litig.*, Civ. A. No. 05-1151, 2006 WL 8460903, at *4 (D.N.J. Jan.

20, 2006) ("It is . . . without dispute that SEC Forms 4 and 5 are in fact SEC filings contemplated by *Oran*"); *In re Astea Int'l Inc. Sec. Litig.*, Civ. A. No. 06-1467, 2007 WL 2306586, at *14 (E.D. Pa. Aug. 9, 2007) (taking judicial notice of Form 4 as a "document[] filed with the SEC"). Plaintiffs do not provide contrary authority from this Circuit. (ECF No. 57 at 12.) Accordingly, the Court will take judicial notice of Exhibit U.

Exhibit W is Amarin's Schedule 14A Proxy Statement, dated April 25, 2019. Plaintiffs extensively cite this exhibit as part of their scienter allegations (*see* ECF No. 43 ¶¶ 110, 123–27) and courts in this Circuit take judicial notice of information in proxy statements filed with the SEC. *In re NAHC, Inc. Sec. Litig*., 306 F.3d at 1331 (finding no reversible error when district court took judicial notice of proxy statement); *Laborers' Loc. #231 Pension Fund v. Cowan*, 300 F. Supp. 3d 597, 607 (D. Del. 2018) ("[W]e may take judicial notice of the . . . proxy statement filed publicly with the Securities and Exchange Commission."); *In re Astea Int'l Inc. Sec. Litig.*, 2007 WL 2306586, at *14 n.17 (taking judicial notice of the proxy statement because it was a public SEC filing). Accordingly, the Court will take judicial notice of Exhibit W.

The Court will take judicial notice of Exhibit V because courts in this District have found price charts, specifically those compiled by Yahoo Finance, sufficiently reliable. *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d at 273 ("in as much as the [] stock price chart compiled by Yahoo! Finance appears to provide this Court with stock price data compiled by a reliable financial news service, this Court takes judicial notice").

Accordingly, because all of the exhibits are either subject to judicial notice or incorporated by reference in the Amended Complaint, Plaintiffs' first Motion to Strike is **DENIED.**

ii. Plaintiffs' Second Motion to Strike

Plaintiffs' Second Motion to Strike asks the Court to strike two new exhibits (X and Y) introduced by Defendants in their reply and four exhibits (B, J, M, and T) that Defendants previously submitted along with its Motion to Dismiss. (ECF No. 63-1 at 1.) Plaintiffs argue "the exhibits and all of Defendants' arguments derived therefrom in Defendants' MTD Reply should be stricken." (*Id.* at 2.) Alternatively, Plaintiffs ask the Court to "convert Defendants' motion to dismiss into one for summary judgment pursuant to Rule 12(d) and provide Plaintiffs with an opportunity to respond after conducting discovery." (*Id.*) Defendants argue the Second Motion to Strike should be dismissed because it is both substantively and procedurally improper. (ECF No. 64.) Because the Court denied the Motion to Strike Exhibits B, J, M, and T above, the Court will only decide whether Exhibits X and Y should be stricken.

1. Exhibit X: ECF No. 59-1

Plaintiffs first note that Exhibit X is not one document, but three different documents grouped together by Defendants. (ECF No. 63-1 at 5.) Plaintiffs also state Defendants submit Exhibit X "to establish the hearsay 'fact' that the FDA granted expanded approval to Vascepa on December 13, 2019" even though the document "was published 13 months after the Class Period ended." (*Id.* at 6.) According to Plaintiffs, "it is therefore irrelevant to Plaintiffs' underlying claims because it could not have been known by Defendants during the relevant time period and has no bearing on whether Defendants' statements and omissions were misleading at that time." (*Id.*) Further, Plaintiffs assert Exhibit X was "never cited in the [Amended Complaint] and thus does not form the basis of the claims." (*Id.* at 8.) Defendants argue Exhibit X is indisputably authentic, integral to the Amended Complaint, relevant, and not unduly prejudicial. (ECF No. 64 at 4–8.)

Both parties cite to *PTC Therapeutics, Inc. Sec. Litig*. (ECF No. 63-1 at 6–7; ECF No. 64 at 6–7.) In that case, the court decided to deny judicial notice of "SEC filings of [PTC's] competitors . . . and their own 8-K and 10-Q, filed after the close of the class period." *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *3 n.5. The relevant class period was November 6, 2014 to February 23, 2016. *Id.* at *7. PTC sought judicial notice of SEC filings from November 2016 and January 2017, after the class period had closed. *Id.* at *3 n.5. The court denied judicial notice of those documents because they were not relied upon in the amended complaint, were "offered to substantiate two relatively inconsequential contentions," and had low relevance to determining the issue for which the filings were offered—"what was known to PTC at the time it made the alleged misstatements." *Id.* Therefore, the fact that Exhibit X was created after the class period closed does not appear to render the document irrelevant on its own.

However, Exhibit X is not just an SEC filing, it is a collection of three separate documents entered as one exhibit. The three documents include: (1) an FDA press release (ECF No. 59-1 at 2–3); an FDA description of its "Priority Review" proceeding (*id.* at 4); and the FDA-approved label for Vascepa from Amarin's website (*id.* at 5–18). Plaintiffs only dispute the authenticity of 15 of the 18 pages of the exhibit because they are "sourced from Amarin's own Vascepa website, which is clearly not a public governmental record." (ECF No. 65 at 6.) Plaintiffs concede that the other pages of Exhibit X are "two authentic FDA documents." (*Id.* at 7.) While Amarin's website is not a public government record, the FDA approved the label posted from Amarin's website and the "statements contained [within] . . . the label 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'" *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (quoting Fed. R. Evid. 201(b)(2)). Courts in this Circuit have previously permitted judicial notice of such drug labels. *Salvio v. Amgen, Inc.*, 810 F. Supp.

2d 745, 750–51 (W.D. Pa. 2011) (taking judicial notice of a drug's package warning label in granting a motion to dismiss); *Bell v. Boehringer Ingelheim Pharm., Inc.*, Civ. A. No. 17-1153, 2018 WL 2447788, at *3 (W.D. Pa. May 31, 2018) (court taking judicial notice of contents of drug label). Therefore, the facts in the FDA-approved drug label "are not subject to reasonable dispute because" those facts "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," like the FDA. Fed. R. Evid. 201(b)(2). Accordingly, the Court will take judicial notice of Exhibit X.

2. Exhibit Y: Bloomberg Transcript of Conference Call, ECF No. 59-2

Plaintiffs argue Exhibit Y is not judicially noticeable because it is being offered for an inadmissible hearsay purpose. (ECF No. 63-1 at 9.) Plaintiffs also assert "the transcript's contents are not Generally Known, and the only Readily Verifiable fact from the transcript is what Bloomberg transcribes as having been stated during the call which fact itself is not relevant." (*Id.* at 9–10.) Lastly, Plaintiffs contend the transcript is not incorporated by reference "because the relevant claims are based on Defendants' oral statements—not the written statements made by Bloomberg LLP in its transcript." (*Id.* at 10.)

Defendants argue judicial notice of Exhibit Y is proper because the transcript was cited in the Amended Complaint and because Plaintiffs do not provide any Third Circuit precedent declining to grant judicial notice of a conference call quoted in the pleadings. (ECF No. 64 at 8–10.)

The Amended Complaint quotes large portions of Exhibit Y in its Amended Complaint. (ECF No. 43 ¶¶ 82, 148.) Its citation at Paragraph 82 takes up nearly a page and half of the Amended Complaint. (*Id.* ¶ 82.) Like Exhibit M, analyzed above, Exhibit Y is "*explicitly relied*

upon in the complaint" and will be considered by the Court on the motion to dismiss. *Burlington Coat Factory*, 114 F.3d at 1426.

Plaintiffs cite *In re OSI Pharms., Inc. Sec. Litig*., for the argument that the transcript is not relevant. (ECF No. 63-1 at 9–10.) In that case, the Eastern District of New York declined to take judicial notice of a conference call transcript because "[a]side from the fact that the document was not referenced in the Complaint," the transcript was "not a matter of public record like an SEC filing" and was not "otherwise 'capable of accurate and ready determination from sources whose accuracy cannot reasonably be questioned.'" *In re OSI Pharm., Inc. Sec. Litig.*, Civ. A. No. 04-5505, 2007 WL 9672541, at *5 (E.D.N.Y. Mar. 31, 2007) (citing Fed. R. Evid. 201(b)(2)). This suggests conference call transcripts, especially if quoted in the Complaint, can still be incorporated by reference even if they are not proper subjects for judicial notice.

Lastly, the Court would not be considering the transcripts for their truth. The transcript would only be considered to determine what statements were made during the conference call. *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (citing *Kramer*, F.2d at 774).

Accordingly, because Exhibits X and Y can both be considered for the purposes of deciding the Motion to Dismiss, Plaintiffs' Second Motion to Strike is **DENIED.**

B. Defendants' Motion to Dismiss

To state a claim for securities fraud pursuant to Section 10(b) of the Exchange Act, "plaintiffs must allege (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014) (citations omitted). A "securities fraud claim is subject to the heightened pleading requirements" of Federal Rule of Civil Procedure 9(b).

GSC Partners CDO Fund v. Washington, 368 F.3d 228, 236 (3d Cir. 2004). The Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u, "imposes another layer of factual particularity to allegations of securities fraud." *Id.* at 236–37 (quoting *In re Rockefeller*, 311 F.3d at 217). Pursuant to the PSLRA, a complaint shall specify "each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." *Id.* at 237 (quoting 15 U.S.C. § 78u4(b)(1)).

Defendants raise four main arguments in support of their Motion to Dismiss: (1) Plaintiffs failed to plead a misstatement or omission; (2) Plaintiffs failed to plead scienter; (3) Plaintiffs failed to pled loss causation, and (4) Plaintiffs' Section 20(A) claim should be dismissed. Because the Court finds Plaintiffs failed to plead a misstatement or omission or scienter, the Court will not address whether Plaintiffs adequately pled loss causation.

i. Misstatement or Omission

Defendants contend Plaintiffs fail to allege either alleged omission—that patients in the placebo group experienced an increase in lipid markers and REDUCE-IT did not reveal the mechanism by which Vascepa worked—rendered Amarin's affirmative statements about its top-line results false. (ECF No. 51-25 at 15–16.)

1. First Alleged Misstatement/Omission: Failure to Disclose Increase in Lipidmarkers

This first alleged misstatement contains two sub-arguments: (1) Defendants failed to disclose the risk that the treatment effect of Vascepa might be overstated and (2) Defendants' dissemination of top-line results failed to disclose the Adverse REDUCE-IT data.

Defendants argue "Plaintiffs do not and cannot identify any misleading Class Period statements regarding LDL-C or the other biomarkers." (*Id.* at 16.) Relatedly, Defendants note its

positive statements about study results "did not foreclose the possibility that LDL and other lipid markers may have increased and because Amarin had a reasonable basis . . . to believe in its study results." (*Id.* at 18.) Defendants also insist it repeatedly warned that the mineral oil placebo might not be biologically inert, which forecloses Plaintiffs' claim that Defendants concealed the fact that the placebo was not inert. (*Id.* at 20.)

Plaintiffs contend Defendants' risk factor statements were misleading "because they failed to disclose the then-existing material facts that increased the likelihood that the risk would transpire, *i.e.*, the Adverse REDUCE-IT Data increased the risk that the purported treatment effect was overstated." (*Id.* at 25.) Specifically, Plaintiffs note that, while Defendants "warned generally that mineral oil might not be inert and that issues arose in the ANCHOR Trial," they did not "disclose the new Adverse REDUCE-IT Data and the unique risks the data posed." (*Id.* at 26.)

"[F]or an omission or misstatement to be actionable under Section 10(b) it is not enough that plaintiff identify the omission or misstatement. The omission or misstatement must also be material, *i.e.*, something that would alter the total mix of relevant information for a reasonable investor making an investment decision." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1425–26 (citing *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 714 (3d Cir. 1996)); *see also City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp*, 908 F.3d 872, 882 (3d Cir. 2018) ("Under Rule 10b–5, the misleading nature of a statement is evaluated 'in the light of the circumstances under which' it is made." (citing 17 C.F.R. § 240.10b-5(b))). "[T]he PSLRA's particularized pleading standard requires that 'the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading.'" *In re Allergan Generic Drug Pricing Sec. Litig.*, Civ. A. No. 169449, 2019 WL 3562134, at *7 (D.N.J. Aug. 6, 2019) (citing 15 U.S.C. § 78u-4(b)(1)); *SLF Holdings, LLC v. Uniti Fiber Holdings, Inc.*, Civ. A. No.

19-1813, 2020 WL 6484310, at *5 (D. Del. Nov. 4, 2020) ("To state a claim [under Rule 10b-5], a plaintiff must identify affirmative statements that were plausibly rendered misleading by the alleged omissions" (citing *City of Edinburg Council v. Pfizer, Inc.*, 745 F.3d 159, 174 (3d Cir. 2014)).

While "omissions can give rise to liability, Section 10(b) and Rule 10b–5 'do not create an affirmative duty to disclose any and all material information.'" *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, Civ. A. No. 216-06509, 2018 WL 3772675, at *15 (D.N.J. Aug. 8, 2018) (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011)). That is, disclosure is only necessary to prevent misleading statements. *See id.*; *see also Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017) (noting that Section 10(b) and Rule 10b-5 require disclosure "only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" (quoting *Matrixx*, 563 U.S. at 44)).

Here, Plaintiffs argue they allege Defendants "concealed information undermining its opinions about Vascepa's efficacy and likely market adoption." (ECF No. 53 at 18.) Plaintiffs' Amended Complaint recounts the press release following the REDUCE-IT study, where "Amarin, Thero, and Granowitz touted the outcome of the trial." (ECF No. 43 ¶ 71.) Plaintiffs highlight the study's general results, which indicated that Vascepa operated much better than a placebo in reducing major adverse cardiovascular events. (*See id.*) Further, Plaintiffs emphasize statements made at the press release in response to the study's results which are challenged by Plaintiffs as false or misleading. (*See id.*) These statements include Thero projecting "REDUCE-IT results could lead to a new paradigm in treatment" and noting "REDUCE-IT topline results stand alone as positive and confirm our hypothesis that pure EPA Vascepa . . . can provide additional cardiovascular risk reduction benefit on top of LDL-C control with standard of care statin therapy

in studied patients." (*Id.*) Plaintiffs also allege Defendants held a conference call where further statements were made regarding the study's topline results, which "position[] Vascepa as the single, most significant advance in preventative cardiovascular drug therapy since the advent of statin therapy." (*Id.* ¶ 72.) Another statement Plaintiffs repeatedly highlight in their Amended Complaint is "the topline results . . . are, indeed, very positive and representative of an overall robust study result." (*Id.*) Plaintiffs highlight many other allegedly misleading statements by Defendants during this conference call, but many of them are reiterations of the statements the Court has noted above. (*See id.* ¶¶ 72, 74.) Plaintiffs also report the market's reactions to the press release, which were unsurprisingly positive in light of the study's success. (*See id.* ¶¶ 75–76.) Based on these statements, Plaintiffs allege "if the mineral oil had interfered with the statins in the placebo arm, the purported treatment effect, and thus the relative risk reduction, would have been far less significant than Amarin and the Officer Defendants initially reported, yet Amarin and the Officer Defendants failed to disclose this risk." (*See id.* ¶ 83.)

Courts in this Circuit have adjudicated issues dealing with statements by Defendants concerning their use of mineral oil as a placebo. In *In re Amarin Corp. PLC.*, (hereinafter "*Amarin I*") the Court considered, in part, allegations that Amarin suppressed concerns regarding the use of mineral oil as a placebo in the ANCHOR trial, one of Amarin's earlier studies involving Vascepa. Civ. A. No. 13-6663, 2015 WL 3954190 (D.N.J. June 29, 2015). The court found the defendants' statements about the progress and probability of success not "materially false or misleading at the time they were made, for multiple reasons." *Id.* at *8. These reasons included the plaintiff's failure to plead "that any FDA concerns about the mineral oil placebo were so serious as to place the ANCHOR trial, and thus, FDA approval of the ANCHOR indication, in jeopardy," failure to plead "that Defendants' statements expressing optimism about the ANCHOR trial's progress were

materially false or misleading so as to require disclosure of those concerns" and failure to plead "when the FDA expressed its concerns to Amarin about the mineral oil placebo." *Id.* Taken together, the court concluded the plaintiff's allegations could not sustain a 10b-5 action, and the plaintiff's complaint was dismissed without prejudice. *Id.*

The plaintiff then filed an amended complaint alleging new facts, including "statements regarding the mineral oil placebo in the ANCHOR study." *In re Amarin Corp. PLC Sec. Litig.*, Civ. A. No. 136663, 2016 WL 1644623, at *9 (D.N.J. Apr. 26, 2016), *aff'd*, 689 F. App'x 124 (3d Cir. 2017) (hereinafter "*Amarin II*"). The plaintiff provided two new allegations in its second amended complaint: (1) the FDA "likely" expressed concern to Amarin that mineral oil was not an inert placebo after the release of the ANCHOR study and prior to the REDUCE-IT study and (2) the FDA informed Amarin that its test results would have to be "robust" to justify consideration for FDA approval. *Id.* at *18. First, the court found the allegation that discussions "likely" took place between the two studies insufficient to satisfy Rule 9(b) and the PSLRA's heightened pleading standard. *Id.* (internal citations omitted). Further, the court found the plaintiff's allegations still failed to demonstrate the FDA's concerns about the mineral oil placebo "were so serious as to place the ANCHOR study and, thus, FDA approval of the ANCHOR indication, in jeopardy." *Id.* Lastly, the court noted plaintiff's argument that the uncertainty provided by using mineral oil as a placebo placed the ANCHOR study in jeopardy was "tenuous at best, and . . . directly contradicted by the fact that the FDA approved the use of mineral oil as a placebo in" a previous Special Protocol Agreement in 2009. *Id.* The plaintiff then appealed the denial of its claims to the Third Circuit, which affirmed the district court's decision. *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 133 (3d Cir. 2017).

In *Jaroslawicz v. M&T Bank Corp.*, the Third Circuit noted "'to avoid exposure for omissions,' a speaker 'need only divulge an opinion's basis, or else make clear the real tentativeness of its belief.'" 912 F.3d 96, 106 (3d Cir. 2018) (citing *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 195 (2015)). While quoting *Omnicare* throughout its decision, the court also explicitly stated "[w]e have yet to decide whether *Omnicare* applies to claims brought under the Exchange Act" and "[w]e decline to do so again today because, even assuming *Omnicare*'s applicability, the shareholders failed to plausibly allege an actionably misleading opinion." *Id.* at 113.

Plaintiffs argue *Jaroslawicz* is distinguishable from this case, "because the plaintiffs there argued that defendants should have disclosed that the due diligence for an acquisition only lasted 5 days, but that exact information, that diligence lasted 5 days, was disclosed in the proxy statement." (ECF No. 53 at 27 n.23 (citing *Jaroslawicz*, 912 F.3d at 112).) Essentially, Plaintiffs argue this distinction because Defendants' warnings "misleadingly failed to disclose the risks facing Amarin due to the Adverse REDUCE-IT Data." (*Id.* at 20.)

Exhibit B, which was attached to Defendants' brief in support of their motion, refers to a discussion with the FDA regarding the safety and efficacy of data observed in the ANCHOR trial. This exhibit notes nominally statistically significant changes "in the placebo group, raising the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) was not biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial." (Exhibit B at 9.) Defendants also repeated this warning, that mineral oil may affect results, after it disclosed its top-line results. (Exhibit J. at 63.) Through these disclosures, Defendants warned of the exact risk Plaintiffs argue they failed to disclose—that the use of mineral oil as a placebo may exaggerate the effect of

Vascepa in the REDUCE-IT trial. Like *Jaroslawicz*, Defendants disclosed the exact information Plaintiffs argue should have been disclosed. Therefore, Plaintiffs' argument that Defendants failed to disclose this risk is unpersuasive.

Plaintiffs also allege Defendants' failure to disclose the increase in LDL-C and other biomarkers in the placebo group renders Defendants' affirmative statement that the REDUCE-IT trial showed Vascepa demonstrated a 25% reduction in cardiovascular events compared to a placebo false or misleading because the increase in LDL-C levels "may have caused" certain levels in the placebo arm to increase by sizeable amounts, "thereby potentially raising the rate of major cardiovascular events in the control group." (ECF No. 43 ¶ 139.) Defendants argue these allegations are similar to those dismissed by the Court in the previous *Amarin* litigation. (ECF No. 51-25 at 18.) In *Amarin II*, the plaintiffs alleged Amarin misled investors by stating its study "achieved its primary and secondary endpoints" because the study was "anything but robust" due to "uncertainty caused by the use of mineral oil, and the adverse test results experienced by patients while on placebo." 2016 WL 1644623, at *18 (citing plaintiff's Second Amended Complaint ¶ 105.) The court dismissed these claims because it found the argument "tenuous at best" and was "directly contradicted by the fact that the FDA approved the use of mineral oil as a placebo in the 2009 SPA." *Id.* However, Plaintiffs correctly point out the omission theory of liability in the previous *Amarin* cases was based on information bearing on FDA approval—which is certainly different from its theory here that Defendants concealed information impacting Vascepa's efficacy. Therefore, the Court will not dismiss on this basis alone.

Further, Plaintiffs argue Defendants "put the Adverse REDUCE-IT Data and attendant risks into play" by referring to REDUCE-IT's "overall results." (ECF No. 53 at 19 (citing *Matrixx*, 563 U.S. at 47).) Plaintiffs contend during an earnings call, "Thero directly referenced the Adverse

REDUCE-IT data when he stated that [Defendants] are 'looking forward to presenting the results in detail at the AHA' and 'we think that those details will be helpful to physicians.'" (*Id.* (citing ECF No. 43 ¶ 82.) Plaintiffs assert because "the biomarkers and mechanism of action were part of the overall study results and were discussed at the AHA presentation, they were put into play" by referencing the overall results. (*Id.* at 19.) From this, Plaintiffs argue when "speaking about the REDUCE-IT results, the defendants literally went beyond the topline results by referencing the 'overall' study results, and the impact the results would have on the drug market, patients, and FDA approval." (*Id.* at 20.)

Exhibit Y provides a transcript of the earnings call Plaintiffs quote. The transcript indicates during the call Defendants spoke about their top-line results and did not go further. On the call, Thero states "[f]ollowing our announcement of top-line results on September 24, we have repeatedly stated that we look forward to presentation of additional details at the AHA Scientific Sessions" and clarifies "[w]e will not be announcing further results of the REDUCE-IT study on this call today." (ECF No. 59-2 at 2.) In addition, the quote from the call Plaintiffs cite came in response to a question from an analyst to Thero, who concluded his answer by stating "[s]o, we are looking forward to presenting the results in detail at the American Heart Association, and we think that those details will be helpful to physicians in the end." (*Id.* at 11.) Even if Defendants did mention overall study results, there is no explicit reference or affirmative characterization of the lipid biomarkers such that they would be put "in play." *See Oran*, 226 F.3d at 285. Merely announcing that results would be presented in the future does not put those results in play either. *See, e.g.*, *Biondolillo v. Roche Holding Ag*, Civ. A. No. 17-4056, 2018 WL 4562464, at *2, *6 (D.N.J. Sept. 24, 2018). Additionally, dissemination of top-line results does not trigger a duty to disclose the full results of a study. *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 569 (E.D.

Pa. 2009) (dismissing Rule 10b-5 claim when "Defendants consistently stated that they would only discuss the top-line results" and warned investors about drawing conclusions about a drug's success); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 879 n.7 (9th Cir. 2012) (noting "Plaintiff is incorrect" that "parties conducting clinical trials necessarily are required to release all the detailed data . . . that may be of interest to investors" because "Section 10(b) and Rule 10b-5 do not categorically prohibit statements that are incomplete or that report cumulative figures instead of detailed breakdowns of the underlying data or subcategories of data"). Because Defendants disclosed the risk that mineral oil could exaggerate Vascepa's effect, did not put the Adverse REDUCE-IT data "in play," and merely reported their top-line results, Defendants' alleged failure to disclose the increase in lipid markers in the placebo arm does not give rise to a claim under Section 10(b) or Rule 10b-5.

2. Second Alleged Misstatement/Omission: Defendants' Failure to Describe Vascepa's Mechanism of Action

Defendants argue "determining the mechanisms responsible for the benefit shown in REDUCE-IT was not the focus of the REDUCE-IT study." (ECF No. 51-25 at 27.) After releasing its top-line results, Defendants disclosed "the effects . . . may be due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together." (Ex. J. at 35.) Defendants also note "[n]ot fully understanding mechanisms of action is not uncommon as the same is true for many drugs including widely used products such as aspirin, statins and metformin." (ECF No. 51-25 at 28.)

Plaintiffs assert "the fact that the purported benefit observed in REDUCE-IT could have been achieved from a host of different factors was problematic because it increased the likelihood that the risk reduction was just a fluke." (ECF No. 53 at 27–28.) As a result, "the inability to identify the mechanism of action from this data undermined Defendants' opinions that Vascepa

was the cause of the risk reduction." (*Id.* at 28.) Plaintiffs also argue the Forbes article, Exhibit M, demonstrates "the significance of the missing mechanism of action." (*Id.* at 27.)

The PSLRA requires Plaintiffs to "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Plaintiffs do not meet this heightened pleading standard, nor can they. Defendants never purported to know the exact mechanism underlying Vascepa's function, and they disclosed this fact.

The Forbes article simply highlights what Defendants disclosed—that Vascepa's mechanism is not entirely known. (*See* Ex. M. at 2, 3 (noting cardiologists "are puzzled as to how Vascepa works" and one cardiologist observing "what we're missing is a mechanism for what's going on").) One of the cardiologists cited even noted the lack of one certain mechanism of action is "a positive" because EPA, the active ingredient in Vascepa, "has other properties aside from lowering triglycerides" which may include "effects on inflammation, effect on blood thinning, and even changes to cellular membranes that might prevent sudden cardiac death." (*Id.* at 4.) Because Plaintiffs do not direct the Court to any misstatement regarding Vascepa's mechanism of action or explain how failure to identify a specific mechanism of action rendered Defendants' top-line results misleading, Plaintiffs do not state a claim under Section 10(b) or Rule 10b-5.[3]

[3] Because Plaintiffs do not properly plead Defendants made an actionable misstatement or omission, the Court need not address whether Plaintiffs adequately pled loss causation. *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d at 167; *Osio v. DeMane*, Civ. A. No. 05-2283, 2006 WL 2129460, at *12 (D.N.J. June 20, 2006) (noting "the Court need not address the remaining elements of a claim under § 10(b) or Rule 10b-5" because plaintiffs did not properly plead an omission of material fact). Further, the Court finds Plaintiffs failed to state a claim under Section 20(a) because liability under Section 20(a) is derivative of liability under Section 10(b). *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013); *Biondolillo v. Roche Holding AG*, Civ. A. No. 17-4056, 2019 WL 1468140, at *4 (D.N.J. Apr. 3, 2019) ("Because the Second Amended Complaint fails to state a claim under Section 10(b), it also fails to state a claim under Sections 20(a) and 20A.").

3. Omnicare Applicability

An additional issue with Plaintiffs' arguments regarding Defendants' alleged misstatement or omissions is the applicability of *Omnicare*. Plaintiffs posit Defendants' opinions are actionable under *Omnicare*. (ECF No. 53 at 13.) Plaintiffs argue three statements about the trial data were misleading: (1) Defendants' statement that Vascepa caused an approximately 25% relative risk reduction compared to a placebo; (2) that this finding was statistically significant and "could lead to a new paradigm in treatment"; and (3) that these results were supported by a robust study supported by the underlying data. (*Id.* at 15–16.) While Defendants were publicizing the benefits of Vascepa, Defendants were also analyzing contradicting data tied to the mineral-oil placebo, "which Amarin already knew was the subject of the FDA's concerns during the ANCHOR trial and a previous shareholder lawsuit." (*Id.* at 16–17.) Based on this context, Plaintiffs argue, "a reasonable investor hearing Amarin tout the REDUCE-IT results would assume the critical placebo issue had not resurfaced." (*Id.* at 17.) Defendants respond by arguing that *Omnicare* is inapplicable to this case. (ECF No. 58 at 5–6.)

In *Omnicare*, the Supreme Court assessed whether opinions made in a registration statement could be actionable under Section 11 of the Securities Act of 1933. *Omnicare*, 575 U.S. 175. Section 11 states "in case any part of the registration statement, when such part became effective, contained an untrue statement of material fact or omitted to state a material fact required to be stated therein . . . any person acquiring such security may sue." *Id.* at 179 (citing 15 U.S.C. § 77k(a)). The Court made two key findings regarding liability for opinions in registration statements. First, the Court found "a sincere statement of pure opinion is not an 'untrue statement of material fact'" but might be an untrue statement of material fact if that opinion is not sincerely held. *Id.* at 186–87. Second, the Court found "if a registration statement omits material facts about

the issuer's inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself, then § 11's omissions clause creates liability." *Id.* at 189.

The Third Circuit declined to decide whether *Omnicare* applies to claims brought under the Exchange Act, contrary to Plaintiffs' contention "at least one Third Circuit court has applied *Omnicare* to an Exchange Act claim." (ECF No. 53 at 13 n.10); *Jaroslawicz*, 912 F.3d at 113 ("We have yet to decide whether *Omnicare* applies to claims brought under the Exchange Act."). On rehearing, while noting "[t]he Supreme Court's decision in *Omincare* provides the relevant framework," the Third Circuit also clarified "[w]e have not considered whether *Omnicare* applies to claims brought under the Exchange Act . . . . But it is unnecessary to resolve that question here." *Jaroslawicz v. M&T Bank Corp*., 962 F.3d 701, 717 n.16 (3d Cir. 2020), *cert. denied*, No. 20-678, 2021 WL 231655 (U.S. Jan. 25, 2021). The Third Circuit has similarly declined to decide this issue in other cases. *See In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x at 132 n.12 (3d Cir. 2017) ("[W]e decline to decide whether *Omnicare* is applicable to § 10(b) claims because . . . our decision here would remain unchanged . . . ."); *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 493 n.11 (3d Cir. 2016). Because the Court has already found Plaintiffs failed to state a claim, it is unnecessary to decide whether *Omnicare* applies.

ii. Scienter

Plaintiffs' Amended Complaint also fails to state a claim because it fails to adequately allege Defendants acted with scienter. "Under the PSLRA's second pleading requirement, a plaintiff must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Institutional Invs. Grp. v. Avaya, Inc.,* 564 F.3d 242, 267 (3d Cir. 2009) (quoting 15 U.S.C. § 78u–4(b)(2)). "[P]laintiffs may establish a 'strong inference'

that the defendants acted with 'scienter' 'either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004) (quoting *In re Burlington*, 114 F.3d at 1418). Plaintiffs must support their allegations of motive with facts stated with particularity. *Id.* Plaintiffs cannot merely plead defendants had a motive "generally possessed by most corporate directors and officers," but "must assert a concrete and personal benefit to the individual defendants resulting from [the alleged] fraud." *Id.* (quoting *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001)). If plaintiffs cannot adequately plead motive, they must "allege specific facts that constitute 'strong circumstantial evidence of conscious misbehavior or recklessness.'" *Id.* at 238 (quoting *Oran*, 226 F.3d at 288–89). "The inquiry is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007). To survive a motion to dismiss, plaintiffs must plead facts that allow "a reasonable person [to] deem the inference of scienter cogent and at least as compelling as any plausible opposing inference once could draw from the facts alleged." *Id.*

Defendants argue Plaintiffs' allegations in the Amended Complaint are insufficient to establish scienter. (ECF No. 51-25 at 29.) Within this general argument, Defendants make several supporting assertions. First, Defendants contend their stock sales weigh against an inference of scienter because a majority of the individual defendants did not sell stock during the class period, the sales were made "pursuant to a written trading plan enacted pursuant to SEC Rule 10b5-1," Defendants sold stock well below the class period high, and because, when taking exercisable stock options into consideration, Defendants' stock sales were a much smaller portion of its overall

holdings. (*Id.* at 29–33.) Second, Defendants argue performance-based executive bonuses do not establish motive to deceive. (*Id.* at 33–34.) And third, Defendants contend Plaintiffs cannot allege that "the Individual Defendants did not actually believe their positive statements about REDUCE-IT" since the statements at issue "are statements of opinion." (*Id.* at 34.)

Plaintiffs argue the fact that Defendants engaged in "conscious misbehavior or recklessness" by (1) knowing and having access to the Adverse REDUCE-IT data when they announced the trial's results; (2) knowing that publicizing only the limited results would mislead investors; and (3) being aware of Amarin's core operations. (ECF No. 53 at 30–34.) Additionally, Plaintiffs assert Defendants had a motive an opportunity to commit fraud through (1) Defendants' suspicious and unusual class period sales; and (2) Defendants' stretch goal bonuses. (*Id.* at 34–37.)

Plaintiffs cite *In re PTC Therapeutics* for the argument "where, as here, a defendant's statements 'implied they had first-hand knowledge' of the matter at issue, such allegations raise a strong inference of scienter." (ECF No. 53 at 30 (citing *In re PTC Therapeutics*, 2017 WL 3705801, at *17).) However, in that case, the "strong inference" of scienter was provided by allegations that the defendants "repeated and confidently told investors that the 'totality' and 'consistency' of the clinical data met FDA standards" even though defendants allegedly knew the clinical data were not "even facially sufficient" to meet FDA standards. *In re PTC Therapeutics*, 2017 WL 3705801, at *16. The court found those facts "if true, suggest more than mere optimism, and support a strong inference that [the defendant's] statements were made knowingly or recklessly." *Id.* The defendants' "statements to investors during earnings calls and healthcare conferences implied that they had first-hand knowledge" of the adverse study results at issue, "while not conclusive" tended to "bolster the inference" that they knew their statements "were false or [were] reckless in disregarding the obvious risk of misleading the public." *Id.* Therefore,

statements implying Defendants' had first-hand knowledge does not "raise a strong inference of scienter" on its own, as Plaintiffs suggest.

Defendants contend "the more cogent and compelling inference is that . . . Defendants believed then (and continue to believe) that the allegedly elevated levels of LDL-C observed in the REDUCE-IT placebo group and the causal mechanism question did not alter the exceedingly positive results." (ECF No. 51-25 at 38–39.) Plaintiffs assert this argument "miss[es] the point," because under *Omnicare*, "Defendants need not have disbelieved their statements to have misled investors" since "Plaintiffs need only show Defendants had 'knowledge of facts or access to information contradicting their public statements.'" (ECF No. 53 at 31 (citing *Nat'l Junior Baseball League v. Pharmanet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 553 (D.N.J. 2010).) However, as noted above, the Third Circuit has declined to hold *Omnicare* applies to cases brought under Section 10(b). Further, *Omnicare* involved alleged violations under Section 11, a strict liability statute. *Omnicare*, 575 U.S. at 175; *Obasi Inv. LTD v. Tibet Pharm., Inc*, 931 F.3d 179, 182 (3d Cir. 2019) ("Section 11 imposes near-strict liability for untruths and omissions made in a registration statement . . . . Unlike antifraud cases, a § 11 plaintiff need not allege scienter, reliance, or loss causation") (citations omitted). Tellingly, *Omnicare* noted requiring § 11 plaintiffs to plead defendants did not actually believe their statements would mislead investors "would ill-fit Congress's decision to establish a strict liability offense." *Omnicare*, 575 U.S. at 193. Therefore, Plaintiffs' reliance on *Omnicare* is unpersuasive.

Further, a plaintiff aiming to allege a strong inference of scienter through circumstantial evidence, as Plaintiffs' allegations and citations suggest here, "must sufficiently plead 'defendants' knowledge of facts or access to information contradicting their public statements . . . . i.e., that defendants knew or . . . should have known that they were misrepresenting material facts to the

corporation.'" *Nat'l Junior Baseball League*, 720 F. Supp. 2d at 553 (quoting *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001)). Importantly, when plaintiffs choose to establish scienter by circumstantial evidence "the strength of the circumstantial allegations must be even greater." *Id.* (quoting *Intelligroup*, 527 F. Supp. 2d at 285)). Plaintiffs allege "publicizing only the efficacy results that claimed a 25% reduction of major adverse cardiovascular events on top of statin therapy was false and misleading" because the full data set, which Defendants had knowledge of, "called into question the proclaimed results of a 25%" decrease in cardiac outcomes. (ECF No. 43 ¶ 139.) Plaintiffs argue they "have sufficiently pleaded Defendants' knowledge of the Adverse REDUCE-IT Data." (ECF No. 53 at 31.) However, Plaintiffs do not demonstrate how knowledge of the Adverse REDUCE-IT Data contradicted Defendants' public statements about Vascepa's success or rendered those public statements false. Each time Defendants made public statements about REDUCE-IT's success, they clarified the study demonstrated an "approximately 25% relative risk reduction." (ECF No. 43 ¶¶ 71, 72, 74, 79, 80, 82.) Importantly, a 25% risk reduction is supported by facts contained with Exhibit X—a document subject to judicial notice. Exhibit X describes the FDA's approval of Vascepa and notes "Vascepa's efficacy and safety were established in" the REDUCE-IT study. (Ex X. at 1.) Exhibit X also includes the FDA-approved drug label for Vascepa, which highlights the findings of REDUCE-IT. (Ex. X. at 5–18.) A summary of the study indicates an approximately 25% risk reduction was met in the primary endpoints. (Ex. X at 15.) Even if Defendants had full access to the Adverse REDUCE-IT data, Plaintiffs do not provide sufficient allegations to support a "strong inference" of scienter. *See* 15 U.S.C. § 78u–4(b)(2).

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' Motions to Strike (ECF Nos. 52, 63) are **DENIED** and Defendants' Motion to Dismiss (ECF No. 51) is **GRANTED without prejudice.** An appropriate Order will follow.

Date: March 29, 2021

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE